

## Notice of Allowability

Application No.

09/786,492

Examiner

Frederick Krass

Applicant(s)

BAKER ET AL.

Art Unit

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment dated 1/13/07.
2. ☒ The allowed claim(s) is/are 1, 3-13, 17, 18, 24 and 26-47.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 1/13/07; 8/11/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3/31/07.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
Frederick Krass  
Primary Examiner  
Art Unit: 1614

### **Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dara Dinner on March 21, 2007.

The following changes have been made:

- 1) Claim 1, first line, "the" has been deleted.
- 2) Claim 1, first line, immediately after "erosion" there has been inserted --- caused by acid in orally administered compositions ---
- 3) Claim 1, line six, immediately after "polysaccharide" (but before the semicolon) there has been inserted --- selected from the group consisting of an alginate, locust bean gum, gellan gum, guar gum, gum arabic, tragacanth, carrageenin, acacia gum, xanthan gum, pectin, cellulose gum, or a combination or mixture thereof ----
- 4) Claim 2 has been canceled without prejudice thereto.

Art Unit: 1614

5) Claim 3, first line, "2" has been changed to --- 1 ---

6) Claim 3, last line, immediately after "xanthan" there has been inserted --- gum

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7) Claim 7, second line, "source" has been changed to --- compound ---

8) Claims 12, 32, 38 and 47, second line of each claim, in each instance a space has been inserted between "4%" and "w/w".

9) Claim 13, second line, the dash (between "composition" and "comprising") has been deleted.

10) Claim 13, third line, immediately after "first" there has been inserted ---  
acidic --

11) Claim 13, fifth line, immediately after "material" (but before the semicolon) there has been inserted --- selected from the group consisting of an alginate, locust bean gum, gellan gum, guar gum, gum arabic, tragacanth, carrageenin, acacia gum, xanthan gum, pectin, cellulose gum, or a combination or mixture thereof ---

12) Claims 17 and 18, third line of each claim, in each instance immediately after "first" there has been inserted --- acidic ---

Art Unit: 1614

13) Claim 18, sixth line, "and an acidulant" has been deleted.

14) Claim 18, eighth line, "or" has been changed to --- of ---

15) Claim 24, first line, "composition" has been changed to --- method ---

16) Claim 24, second line, "w/w" has been changed to --- w/v ---

17) Claim 25 has been canceled without prejudice thereto.

18) Claim 26, first line, "25" has been changed to --- 13 ---.

In the specification, the last lines on pages 5-8 and 15 are blurred such that a problem could arise when printing the patent. Accordingly, the lines are "amended" as follows:

19) Page 5, last line, the line has been "amended" to read --- A further advantage arises from the use of low levels of calcium, suitably in the ---

20) Page 6, last line, the line has been "amended" to read --- calcium in the range 0 to 0.8 mol per mol of acid, wherein the effective pH of the ---

Art Unit: 1614

21) Page 7, last line, the line has been “amended” to read --- (35/65% w/w) mixture sold under trade name Grinstead JU543 from Danusco ---

22) Page 8, last line, the line has been “amended” to read --- exposure period as compared to the beverage with xanthan gum which gave an ---

23) Page 15, last line, the line has been “amended” to read --- adjusted to 5 litres with water. The pH was corrected with 3.4 with 1M sodium ---

#### **Reasons for Allowance**

The following is an examiner’s statement of reasons for allowance:

The instant claims were amended (by examiner’s amendment) to insure that they are commensurate in scope with the evidence presented in the specification as discussed infra, thereby providing a clear line of demarcation over the prior art of record. By limiting the instant claims to hydrocolloids (for which unexpected results have been experimentally demonstrated, as also discussed infra), it is believed that any potential issues of obviousness-type double patenting which might theoretically be raised will be rendered moot as well.

As factually verified by the instant specification, hydrocolloids (termed “food grade complex polysaccharide stabilizers and thickening agents” by applicant at the first paragraph of page 3) are able to lower tooth erosion potential when added to acidic oral compositions. See, e.g., page 6, lines 16-21. An extensive and representative sampling of

Art Unit: 1614

these hydrocolloids was experimentally tested, including cellulose gums. See page 8, line 3, and page 9, line 33 (cellulose gums); see also the table bridging pages 11 and 12.

Furthermore, the instant specification demonstrates that combinations of calcium and polysaccharide hydrocolloids unexpectedly lower tooth erosion potential in a synergistic fashion. See page 2, lines 9-15 and example 7 at pages 14 and 15. Nothing in the prior art (including any commonly assigned copending applications or patents) indicates that these particular thickeners would be able to reduce tooth erosion potential, let alone provide synergistic inhibition when combined with at least 0.01 moles calcium per mole of acid. (Note that all claims reciting polysaccharide hydrocolloids require the presence of at least 0.01 moles calcium). The specification also factually demonstrates that the synthetic hydrocolloid polyvinylpyrrolidone unexpectedly provides increased resistance to tooth erosion. See page 3, lines 6 and 7, and example 11 at page 17.

Hydrocolloids are generally known as thickeners for beverages, as illustrated by various references cited on the latest Information Disclosure Statement and as previously admitted by applicant at page 1, lines 20-26 of the instant specification. None of the prior art of record recognizes, however, that hydrocolloids are able to lower the tooth erosion potential of acidic oral compositions. Accordingly, none of the prior art suggests, teaches or discloses the addition of hydrocolloids to acidic oral compositions to reduce their tooth erosion potential. This requires not simply the addition of a hydrocolloid but also the judicious selection of the proper type and concentration required for a given particular oral composition, coupled with controlling or adjusting the "effective pH" necessary to reduce tooth erosion potential as well. See the instant specification at page 2, lines 26-31;

Art Unit: 1614

the passage bridging page 3, line 26 to page 4, line 9; the passage bridging page 4, line 31 to page 5, line 17.

Accordingly, the methods of the prior art are clearly distinguished from all prior art of record, including the various commonly assigned, copending applications and patents. None of the prior art of record fairly suggests, teaches or discloses the particular order of addition suggested by the instant claims, nor the selection of hydrocolloids to lower tooth erosion potential. Nor would one reasonably expect the instantly claimed methods to be inherent in any of the prior art disclosures, given the extensive amount of "picking and choosing" necessary to arrive at same as outlined in the preceding paragraph. And finally, nothing in the prior art suggests the unexpected synergistic results obtained when using a combination of polysaccharide hydrocolloid and calcium in an amount of at least 0.1 mole per mole of acid, nor does any of the prior art of record suggest that polyvinylpyrrolidone has any relevant activity, let alone the ability to reduce tooth erosion.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Examiner's Comment**

The examiner notes that an updated copy of the Form 1449 submitted 08/11/06 has been included with this communication, since the copy previously submitted was inadvertently not signed by the examiner on page 2.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Art Unit: 1614

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Fred Krass', written in a cursive style.